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I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on November 4, 1996


Nancy J. Roberts

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Lynn E. Spitler et al.

Serial No.: 08/288,057

Filing Date: 10 August 1994

For: PROSTATIC CANCER VACCINE

Examiner: P. Gambel

Group Art Unit: 1816

**DECLARATION OF MICHAEL MASTRANGELO, MD
PURSUANT TO 37 C.F.R § 1.132**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Michael Mastrangelo, MD, declare as follows:

1. I am a Professor of Medicine, and Associate Clinical Director of the Jefferson Cancer Center in Philadelphia, Pennsylvania. A copy of my *Curriculum Vitae* is attached hereto as Exhibit A. I am Chairman of the Scientific Advisory Board of Jenner Technologies, the assignee in this application, and a shareholder in the company.

2. I have reviewed the Declaration Under 37 C.F.R. 1.132 prepared by Dr. Lynn E. Spitler describing the results of a clinical study directed to the use of prostate specific antigen (PSA) as an active ingredient in an antiprostata cancer vaccine. I am also familiar with the study itself, and with the results that were obtained.

3. The purpose of the study was to obtain evidence that the vaccines would raise a sufficient cellular immune response to have a beneficial effect with respect to prostate tumors. Such a result could be shown directly by measuring cytotoxic lymphocyte (CTL) generation; however, I am aware that this was not possible in these studies because the assay was not satisfactory because of the lack of an appropriate target cell for the assay.

4. The responses measured are understood in the art to be satisfactory substitutes for measuring CTLs. Thus, the proliferation of lymphocytes from two of the patients in response to contact with PSA or in response to peptides representing putative PSA epitopes is indicative of an appropriate cellular immune response. The ability of PSA or PSA derived peptides to stimulate cytokine production -- i.e., gamma interferon and IL-4 production -- from lymphocytes in these patients also indicates that the cellular response is obtained specifically with respect to PSA. The observation of the development of a positive skin test response to PSA in one patient is also consistent with these observations showing the development of cell-mediated immunity in the patients.

5. In my opinion, the results obtained in this clinical study provide evidence that the vaccines are likely to be effective in exerting a beneficial effect on patients with prostate tumors or at risk for prostate tumors.

6. The efficacy shown for the vaccine tested in the foregoing clinical studies further provides evidence that analogous vaccines based on host tissue antigen, such as prostate specific membrane antigen (PSMA) and prostate acid phosphatase (PAP) would behave in a similar manner. It is also well known that if the entire antigen is effective as a vaccine, portions of the antigen will be effective as well, especially if manipulated by art-known methods to enhance their immunogenicity, such as by coupling them to carrier.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

October 10, 1996


Michael Mastrangelo, MD

Revised 12/93

CURRICULUM VITAE

NAME: Michael J. Mastrangelo, M.D.

SOCIAL SECURITY NO: 210-28-9391

DATE OF BIRTH: October 3, 1938

MARITAL STATUS: Married 1964 - Ann Sundav

Children:	David M.	1965
	Mark S.	1967
	Audrey A.	1970

EDUCATION

Villanova University, Villanova, PA	
B.S. (Biology), Summa Cum Laude (1/696)	1956-1960
The Johns Hopkins University School of Medicine, M.D.	1960-1964

POSTGRADUATE TRAINING

Thomas Jefferson University Hospital, Philadelphia, PA	
Medical Intern	1964-1965
Medical Resident	1967-1969
American Cancer Society Trainee	1968-1969
Oncology Fellow	1969-1970
Chief Medical Resident	1970-1971
Post-doctoral Fellow	1971-1972
Laboratory of R. T. Prehn, M.D.	
The Institute for Cancer Research	
7701 Burholme Avenue	
Philadelphia, PA 19111	

MILITARY SERVICE

CPT, MC, U.S. Army, Molecular Biology Branch,	
Medical Laboratories, Edgewood Arsenal, MD	1965-1967

SPECIALTY CERTIFICATION

Diplomate of the American Board of Internal Medicine	1972
Certificate #37358	
Diplomate, subspecialty of Medical Oncology	1973
Certificate #37358	

LICENSURE

Maryland - D7736	1964
Pennsylvania - MD 008521-E	1965
New Jersey - MA24857	1971

HONORARY SOCIETIES

Delta Epsilon Sigma	1960
National Collegiate Who's Who	1960
Sigma Xi	1984

Exhibit A

PROFESSIONAL SOCIETIES

College of Physicians of Philadelphia	1971
Philadelphia County Medical Society	1972-1986
Pennsylvania Medical Society	1972-1986
American Medical Association	1972-1986
American Federation for Clinical Research	1972
American Association for the Advancement of Science	1973
American Society of Clinical Oncology	1973
American College of Physicians - Member	1973
- Fellow	1975
American College of Clinical Pharmacology Fellow	1974
American Association for Cancer Research	1974
Program Committee for Immunology - Member	1979-1980
" " " " - Chairperson	1987-1988
Membership Committee	1984-1985
Gertrude Elion Award Committee	1993-1994
Society for Biological Therapy	1981-
Board of Directors	1988-1991
Chairman, Program and Publications Committee	1989-1990
President	1990-1992

PROFESSIONAL ACTIVITIES

Seminars in Oncology - Associate Editor	1974-
Eastern Cooperative Oncology Group - Member	1973-1976
Malignant Melanoma Clinical Cooperative Group - Member	1973-1977
Committee on Tumor Immunotherapy, DCBD, NCI - Member	1975-1979
American Cancer Society, Philadelphia Division	
Member, Professional Education Committee	1975-1977
Member, Board, Northeast Unit	1978-1979
American Cancer Society, National Office	
Member, Advisory Committee on Immunology and Immunotherapy	1987-1991
Philadelphia County Medical Society -	1976-1984
Member, Cancer Control Subcommittee	1976-1977
Experimental Therapeutic Study Section, NIH -	
Member	1980-1982
Chairman I + II	1982-1984
Cancer Immunology and Immunotherapy - Board of Editors	1981-1993
Subcommittee on Biological Response Modifiers of the	1978-1980
Division of Cancer Treatment's Board of Scientific Counsellors	
Biological Response Modifier Program, DCT, NCI -	
Operating Committee, Member	1980-1982
Decision Network Committee, Member	1980-1984
Journal of Biological Response Modifiers - Editorial Board	1982-1990
Journal of Immunotherapy - Editorial Board	1990-
Cancer Research - Associate Editor	1983-1994
Hybridoma - Editorial Board	1987-1992
PDQ - Extramural Board	1989-1993
The United States Pharmacopeial Convention, Inc.	
Advisory Panel on Hematologic and Neoplastic Diseases	1990-1995
Vaccine Research - Associate Editor, Tumor Vaccines	1990-

FACULTY AND APPOINTMENTS

Current -

Professor of Medicine,	1984-
Director, Division Medical Oncology	1984-1993
Member, Division Neoplastic Diseases	1993-
Jefferson Medical College	
1025 Walnut Street	
Philadelphia, PA 19107	

Courtesy Staff	1987-
Associate Staff	1984-1987
Associate Physician (Medicine)	1977-1984
Assistant Physician (Medicine)	1972-1976
Director, Pigmented Lesion Clinic	1972-1984
American Oncologic Hospital	
Central and Shelmire Avenues	
Philadelphia, PA	

Consultant, Oncology	1973-
Department of Medicine	
The Mercer Medical Center	
Trenton, NJ	

Consultant, Oncology Division	1974-
Retina Service	
Wills Eyes Hospital	
Philadelphia, PA	

Prior

Instructor (Medicine)	1970-1974
Assistant Physician (Medicine)	1971-1974
Jefferson Medical College and Hospital	
Philadelphia, PA 19107	

Clinical Associate Professor (Medicine)	1977-1984
Clinical Assistant Professor (Medicine)	1974-1977
School of Medicine	
Temple University Health Science Center	
Philadelphia, PA 19107	

Research Physician	1972-1980
The Institute for Cancer Research	
Philadelphia, PA	

Consultant, Medical Oncology	1976-1986
Doylestown Hospital	
Doylestown, PA	

Consultant, Tumor Immunotherapy	1973-1988
Chestnut Hill Hospital	
Philadelphia, PA	

PUBLICATIONS

APERS

1. Mastrangelo, M.J., Giordano, W.P. and Johnson, R.P. Surface behavior of individual lipids similar to constituents of pulmonary surfactant. EATR 4087, April 1967.
2. Mastrangelo, M.J. and Johnson, R.P. Segmental reversibility and hysteresis of preparations similar to pulmonary surfactant. EATR 4097, May 1967.
3. Mastrangelo, M.J., Carwile, H. and Johnson, R.P. Qualitative protein composition of lung surfactant preparations. EATR 4124, August 1967.
- *4. Weiss, A.J. and Mastrangelo, M.J. Phase I study of a combination of azotomycin (NSC-56654) and 5-Fluorouracil (NSC-19893) in malignant disease. Cancer Chemother Rpt. 54:109-112, 1970.
5. Mastrangelo, M.J. and Weiss, A.J. The chemotherapy of respiratory tract neoplasms. In: Cancer Chemotherapy II. I. Brodsky, S.B. Kahn, J.H. Moyer (Editors), Grune and Stratton, Inc., New York, NY, 1972, pp. 195-208.
- *6. Weiss, A.J., Stambaugh, J.E., Mastrangelo, M.J., Laucius, J.F. and Bellet, R.E. A Phase I study of 5-azacytidine (NSC-102816). Cancer Chemother. Rpt. 56:413-420, 1972.
7. Mastrangelo, M.J., Sulit, H.O., Chee, D. and Engstrom, P.F. Cancer Forum: Malignant Melanoma. Penna. Med. 75:43, 1972.
- *8. Mastrangelo, M.J., Grage, T. Bellet, R.E. and Weiss, A.J. A Phase I study of emetine hydrochloride (NSC-33669) in solid tumors. Cancer 31:1170-1175, 1973.
- *9. Bellet, R.E., Mastrangelo, M.J., Engstrom, P.F. and Custer, R.P. Hepatotoxicity of 5-azacytidine (NSC-102816): A clinical and pathologic study. Neoplasma 20:303-310, 1973.
- *10. Bellet, R.E., Mastrangelo, M.J., Dixon, L.M. and Yarbrow, J.W. A Phase I study of ICRF 159 (NSC-129943) in solid tumors. Cancer Chemother. Rpt. 57:185-189, 1973.
11. Mastrangelo, M.J., Creech, R.H. and Engstrom, P.F. Cancer Forum: Early diagnosis holds promise in lung cancer. Penna. Med. 76:64, 1973.
12. Bornstein, R.S., Mastrangelo, M.J., Sulit, H.L., Chee, D.O., Yarbrow, J.W., Prehn, L.M. and Prehn, R.T. Immunotherapy of melanoma with intralesional BCG. Natl. Cancer Inst. Monogr. 39:213-220, 1973.
- *13. Mastrangelo, M.J., Kim, Y.H., Bornstein, R.S., Chee, D.O., Sulit, H.L., Yarbrow, J.W. and Prehn, R.T. Clinical and histological correlation of melanoma regression following intralesional BCG therapy: A case report. J. Natl. Cancer Inst. 52:19-24, 1974.
- *14. Bellet, R.E., Mastrangelo, M.J., Engstrom, P.F., Strawitz, J.G. and Weiss, A.J. Clinical trial with subcutaneously administered 5-Azacytidine (NSC-102816). Cancer Chemother. Rpt. 58:217-222, 1974.

- *15. Bodurtha, A., Kim, Y.H., Laucius, J.F., Donato, R.A. and Mastrangelo, M.J. Hepatic granulomas and other hepatic lesions associated with BCG immunotherapy for cancer. *Am. J. Clin. Pathol.* 61:747-752, 1974.
- *16. Bellet, R.E., Mastrangelo, M.J. and Dixon, L.M. Letter to the Editor: ICRF 159. *Lancet* 1:926, 1974.
- 17. Mastrangelo, M.J., Laucius, J.F. and Outzen, H.C. Fundamental concepts in tumor immunology: A brief review. *Semin. Oncol.* 1:291-296, 1974.
- *18. Laucius, J.F., Bodurtha, A.J., Mastrangelo, M.J. and Creech, R.H. Bacillus Calmette-Guerin in the treatment of neoplastic disease. *J. Reticuloendothel. Soc.* 16:347-373, 1974. (Abstracted Year Book of Cancer 1976).
- *19. Bodurtha, A.J., Chee, D.O., Laucius, J.F., Mastrangelo, M.J. and Prehn, R.T. Clinical and immunological significance of human melanoma cytotoxic antibody. *Cancer Res.* 38:189-193, 1975.
- *20. Creech, R.H., Catalano, R.B., Mastrangelo, M.J. and Engstrom, P.F. Low dose cyclophosphamide, methotrexate, and 5-fluorouracil therapy of metastatic breast cancer. *Cancer* 35:1101-1107, 1975.
- *21. Mastrangelo, M.J., Bellet, R.E., Berkelhammer, J. and Clark, W.H., Jr. Regression of pulmonary metastatic disease associated with intralesional BCG therapy of dermal melanoma metastases. *Cancer* 36:1305-1308, 1975. (Abstracted Year Book of Diagnostic Radiology 1977).
- *22. Berkelhammer, J., Mastrangelo, M.J., Laucius, J.F., Bodurtha, A.J. and Prehn, R.T. Sequential in vitro reactivity of lymphocytes from melanoma patients receiving immunotherapy compared with the reactivity of lymphocytes from healthy donors. *Int. J. Cancer* 16:571-578, 1975.
- *23. Sieper, W.J., Mastrangelo, M.J. and Bellet, R.E. Phase II study of adriamycin (NSC-123127) in patients with metastatic melanoma. *Cancer Chemother. Rpt.* 59:1181-1182, 1975.
- *24. Pliskin, M.E., Mastrangelo, M.J., Brown, A.M. and Custer, R.P. Melanoma of the maxilla presenting as a gingival swelling. *Oral Surg. Oral Med. Oral Pathol.* 41:101-104, 1976.
- *25. Mastrangelo, M.J., Sulit, H.L., Prehn, L.M., Bornstein, R.S., Yarbrow, J.W. and Prehn, R.T. Intralesional BCG in the treatment of metastatic malignant melanoma. *Cancer* 37:684-692, 1976.
- *26. Bodurtha, A.J., Berkelhammer, J., Kim, Y.H., Laucius, J.F. and Mastrangelo, M.J. A clinical, histological and immunological study of a case of metastatic malignant melanoma undergoing spontaneous remission. *Cancer* 37:735-742, 1976.
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28. Bellet, R.E. and Mastrangelo, M.J. Investigational new drugs. In: Oncologic Medicine, P.F. Engstrom, A.I. Sutnick (Editors), University Park Press, Baltimore, MD, 1976, pp. 237-245.
- *29. Mastrangelo, M.J., Bellet, R.E., Laucius, J.F. and Berkelhammer, J. Immunotherapy of malignant melanoma. A Review. In: Oncologic Medicine, P.F. Engstrom, A.I. Sutnick (Editors), University Park Press, Baltimore, MD, 1976, pp. 71-93.
- *30. Pliskin, M.E., Mastrangelo, M.J., Bellet, R.E. and Berkelhammer, J. BCG immunotherapy of a mucous membrane malignant melanoma (a case report). Oral Surg. Oral Med. Oral Pathol. 42:73-79, 1976.
- *31. Mastrangelo, M.J., Berd, D. and Bellet, R.E. Critical review of previously reported clinical trials of cancer immunotherapy with non-specific immunostimulants. Ann. N.Y. Acad. Sci. 277:94-123, 1976.
- *32. Bellet, R.E., Mastrangelo, M.J., Laucius, J.F. and Bodurtha, A.J. A randomized prospective trial of DTIC (NSC-45388) alone versus BCNU (NSC-409962) plus vincristine (NSC-67574) in the treatment of metastatic malignant melanoma. Cancer Treat. Rpt. 60:595-600, 1976.
33. Mastrangelo, M.J., Berd, D. and Bellet, R.E. Review of immunotherapeutic studies on cancer patients. In: Immuno-Cancerology in Solid Tumors, M. Martin, L. Dionne (Editors), Stratton Intercontinental Medical Book Corporation, New York, NY, 1976, pp. 155-170.
- *34. Bellet, R.E., Catalano, R.B., Danna, V.G., Berkelhammer, J. and Mastrangelo, M.J. A study of antitumor (Phase II) and immunosuppressive effects of ICRF-159 (NSC-129943) in patients with metastatic melanoma. J. Clin. Pharm. 16:433-438, 1976.
- *35. Bellet, R.E., Engstrom, P.F., Catalano, R.B., Creech, R.H. and Mastrangelo, M.J. Phase II study of ICRF-159 (NSC-129943) in patients with metastatic colorectal carcinoma previously exposed to systemic chemotherapy. Cancer Treat. Rpt. 60:1395-1397, 1976.
36. Clark, W.H., Jr., Mastrangelo, M.J., Ainsworth, A.M., Berd, D., Bellet, R.E. and Bernardino, E.A. Current concepts of the biology of human cutaneous malignant melanoma. Adv. Cancer Res. 24:267-338, 1977.
- *37. Berkelhammer, J., Mastrangelo, M.J. and Prehn, R.T. Effect of treatment with dimethyl triazeno imidazole carboxamide (DTIC, NSC-45388) or 1,3-bis(2-chlorethyl)-1-nitrosourea (BCNU, NSC-409962) plus vincristine (NSC-67564) on lymphocyte reactivity of melanoma patients. Cancer Immunol. Immunother. 2:119-125, 1977.
- *38. Laucius, J.F., Patel, Y.A., Koons, L.S., Bellet, R.E. and Mastrangelo, M.J. A Phase II evaluation of Bacillus Calmette-Guerin plus megestrol acetate in patients with metastatic renal adenocarcinoma. Med. Pediatr. Oncol. 3:237-242, 1977.
- *39. Bellet, R.E., Vaisman, I., Mastrangelo, M.J. and Lustbader, E. Multiple primary malignancies in patients with cutaneous melanoma. Cancer 40:1974-1981, 1977.

- *40. Laucius, J.F., Bodurtha, A.J., Mastrangelo, M.J. and Bellet, R.E. A Phase II study of autologous irradiated tumor cells plus BCG in patients with metastatic malignant melanoma. *Cancer* 40:2091-2093, 1977.
41. Mastrangelo, M.J., Bellet, R.E., Berd, D., and Lustbader, E. A randomized prospective trial comparing methyl-CCNU + vincristine to methyl-CCNU + vincristine + BCG + allogeneic tumor cells in patients with metastatic malignant melanoma. *In: Immunotherapy of Cancer: Current Status of Trials in Man*, W. Terry and D. Windhorst (Editors), Progress in Cancer Research and Therapy, Vol. 6, Raven Press, New York, NY, 1978, pp. 95-102.
42. Mastrangelo, M.J., Clark, W.H., Jr., Bellet, R.E. and Berd, D. Cutaneous malignant melanoma: Diagnosis prognosis and conventional therapy. *In: Immunotherapy of Cancer: Current Status of Trials in Man*, W. Terry, D. Windhorst (Editors), Progress in Cancer Research and Therapy, Vol. 6, Raven Press, New York, NY, 1978, pp. 1-17.
43. Engstrom, P.F., Paul, A.R., Catalano, R.B., Mastrangelo, M.J. and Creech, R.H. Fluorouracil versus fluorouracil + BCG in colorectal adenocarcinoma. *In: Immunotherapy of Cancer: Current Status of Trials in Man*, W. Terry, D. Windhorst (Editors), Progress in Cancer Research and Therapy, Vol. 6, Raven Press, New York, NY, 1978, pp. 587-596.
- *44. Bellet, R.E., Catalano, R.B., Mastrangelo, M.J. and Berd, D. Phase II study of subcutaneously administered 5-azacytidine (NSC-102816) in patients with metastatic malignant melanoma. *Med. Pediatr. Oncol.* 4:11-15, 1978.
45. Greene, M.H., Reimer, R.R., Clark, W.H., Jr. and Mastrangelo, M.J. Precursor lesions in familial melanoma. *Semin. Oncol.* 5:85-87, 1978.
- *46. Bellet, R.E., Catalano, R.B., Mastrangelo, M.J., Berd, D. and Koons, L.S. Phase II trial of VM-26 (NSC-122819) in patients with metastatic melanoma. *Cancer Treat. Rpt.* 62:445-447, 1978.
- *47. Clark, W.H., Jr., Reimer, R.R., Green, M., Ainsworth, A.M. and Mastrangelo, M.J. Origin of familial malignant melanoma from heritable melanocytic lesions. The B-K mole syndrome. *Arch. Derm.* 114:732-738, 1978.
48. Berkelhammer, J., Mastrangelo, M.J., Bellet, R.E., Prehn, R.T. and Thibault, L.H. Failure of lymphocyte microcytotoxicity to distinguish relapsers from non-relapse in melanoma patients receiving postsurgical adjuvant chemotherapy. *Eur. J. Cancer* 14:793-798, 1978.
49. Mastrangelo, M.J., Berd, D. and Bellet, R.E. Limitations, obstacles and controversies in the optimal development of immunotherapy. *In: Immunotherapy of Human Cancer*, E. Hersh, J. Sinkovics (Editors), Raven Press, New York, NY, 1978, pp. 375-394.
50. Bellet, R.E., Mastrangelo, M.J., Berd, D. and Lustbader, E. Melanoma chemotherapy. *In: Cancer Chemotherapy III*, I Brodsky, S.B. Kahn, J.F. Conroy (Editors), Grune and Stratton, Inc., New York, 1978, pp. 225-242.
- *51. Mastrangelo, M.J. and Bellet, R.E. Immunotherapy of melanoma. *In: Clinical Therapeutics*, D.T. Lowenthal, D.A. Major II, (Editors), Grune and Stratton, Inc., New York, 1978, pp. 281-291.

- *52. Bellet, R.E., Catalano, R.B., Mastrangelo, M.J. and Berd, D. A positive Phase II trial of dibromodulcitol in patients with metastatic melanoma refractory to DTIC and nitrosourea. *Cancer Treat. Rpt.* 62:2095-2099, 1978.
53. Bellet, R.E., Mastrangelo, M.J. and Berd, D. Chemotherapy of metastatic malignant melanoma. *In: Human Malignant Melanoma*, Grune and Stratton, Inc., New York, 1979, pp. 355-416.
54. Vaisman, I., Mastrangelo, M.J., Bellet, R.E. and Lustbader, E. Primary cutaneous melanoma and coexisting malignant neoplasms. *In: Human Malignant Melanoma*, Grune and Stratton, Inc., New York, 1979, pp. 243-260.
55. Mastrangelo, M.J., Bellet, R.E. and Berd, D. Immunology and immunotherapy of malignant melanoma. *In: Human Malignant Melanoma*, Grune and Stratton, Inc., New York, 1979, pp. 355-416.
56. Mastrangelo, M.J., Bellet, R.E. and Berd, D. Adjuvant therapy. *In: Human Malignant Melanoma*, Grune and Stratton, Inc., New York, 1979, pp. 309-324.
57. Mastrangelo, M.J., Bellet, R.E. and Berd, D. Prognostic Factors. *In: Human Malignant Melanoma*, Grune and Stratton, Inc., New York, 1979, pp. 273-281.
58. Berd, D., Mastrangelo, M.J. and Bellet, R.E. Metastatic uveal melanoma. *In: Human Malignant Melanoma*, Grune and Stratton, Inc., New York, 1979, pp. 489-496.
59. Laucius, J.F. and Mastrangelo, M.J. Cutaneous depigmentary phenomena in patients with malignant melanoma. *In: Human Malignant Melanoma*, Grune and Stratton, Inc., New York, 1979, pp. 209-226.
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- *61. Mastrangelo, M.J., Bellet, R.E. and Berd, D. A Phase III comparison of methyl-CCNU + vincristine with or without BCG + allogeneic tumor cells in metastatic melanoma. *Cancer Immunol. Immunother.* 6:231-236, 1979.
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- 75. Bellet, R.E., Mastrangelo, M.J., Berd, D. and Maguire, H.C. Primary cutaneous melanoma. *In: Concepts in Cancer Medicine*, S.B. Kahn, R. Love, R. Chakravorty, C.W. Sherman (Editors), Grune and Stratton, Inc., New York, 1982, Chapter 9, pp. 545-555.
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ABSTRACTS

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